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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/064,057	04/22/98	GERARD	G 0942.4330002

HM22/0830
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EXAMINER

MONSHIPOURI, M

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 08/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/064,057

Applicant(s)
Gerard et al.

Examiner
Maryam Monshipouri

Group Art Unit
1652



☐ Responsive to communication(s) filed on _____

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 26, 28, 33, 34, 37, 39, 40, and 117-126 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 26, 28, 33, 34, 37, 39, 40, and 117-126 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 17, 21, 20
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claims 1-5, 8, 10, 12-16, 18, 20-23, 41, 43, 46, 51-57, 61-66, 68, 71, 76, 81-85, 87-90, 97-102, 108-110, 112, and 114-116 have been canceled. Claims 26, 28, 37, 33-34, 39-40, and newly presented claims 117-125 are still at issue and are present for examination.

Applicants' arguments filed on 6/14/00, paper No. 19, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 26, 28, 33-34, 37, 39-40 and 117-126 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 190-191 of U.S. Patent No. 6,603,608 (5/16/2000). As mentioned previously although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of claims 190-191

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directed to a method of producing a reverse transcriptase having DNA polymerase activity and reduced RNase H activity in U.S. Patent 6,603, 608 embraces the scope of instant claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 26, 28, 33, 40 and 117-126 remain rejected under 35 U.S.C. 102(b) as being anticipated by Soltis et al. (Proc. Natl. Acad. Sci. U.S.A., 85, 3372-3376, 1988, cited in the IDS).

As mentioned previously, Soltis et al. teach the recombinant preparation of an AMV-RT heterodimer. Said enzyme can be considered to be ASLV because applicant in pages 3-4 of the specification states that ASLV may include Raous Sarcoma Virus (RSV) and Avian Myeloblastosis Virus (AMV). Hence recombinant expression of the entire gene encoding said enzyme (see their materials and Methods section) which implies coexpression of its individual subunits prior to this invention anticipates claim 26, 28, 33, 40 and 117-126. Applicant in traversal of this rejection argued that Soltis et al. report very low activities for individual subunits of ASLV and therefore is not anticipatory to the instant invention. However, Soltis et al. remain anticipatory to instant invention because although Soltis et al. do not disclose specific activities for their AMV-RT preparation, they clearly indicate the purification of their AMV-RT enzyme

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(see page 3374, second column) resulted in specific activities which were 10,000 to 100,000 times higher than those of alpha and beta subunits of ASLV RT. Considering that purified beta subunit of ASLV in table 1 indicates a specific activity of 2.7 units per milligram it is reasonable to deduce that activity of purified AMV-RT to be $2.7 \times 10,000$ (or $\times 100,000$) units per milligram which results in AMV-RT activities of 27,000-270,000 units per milligram which is within the range of RT specific activity (25,000-140,000 units/milligram) claimed here.

5. Claim 26, 28, 34, 37, 39 and 117-126 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chernov et al. (Biomed. Sci., 2, 49-53, 1991, cited in the IDS referred to as "Chernov I"). As mentioned previously, Chernov I (see abstract) teach the recombinant preparation of Rous sarcoma Virus (RSV) RT using E. coli, prior to this invention, anticipating claims 26 and 28 and 117-126. They prepared their RT by mixing different concentrations of individually expressed subunits of said enzyme in solution (see page 51), anticipating claim 34. They also teach that modification of RNase H subunit activity of said enzyme with inhibitors of RNase activity such as azidothymidine triphosphate (see fig 5), anticipating claims 37 and 39. Applicant in traversal of this rejection argued that Chernov I's method of Reverse Transcriptase production is not anticipatory to the instant invention because Chernov I do not teach an enzyme preparation with specific activities claimed here. Applicant then continued by citing Chernov et al.'s earlier publication (Chernov et al., Biokhimiya 55, 586-594, 1990, Chernov II, also cited in the IDS) which reports preparation of purified ASLV RT with specific activities of 20,700 units per milligram and indicated that because of lower specific activities reported Chernov II and its

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subsequent article Chernov I, are not reporting the same production method as claimed here. The examiner of record has to disagree with said arguments because Chernov I in page 53 of their publication discloses that their RT (prepared by the same method as Chernov II) is purified to homogeneity. Considering that in previous publication namely Chernov II, said authors teach the specific activity of their preparation to be at least 20,700 units/milligram it is reasonable to assume that the RT preparation in Chernov I which was purified to homogeneity at least does have a specific activity of 20,700 units/milligram which is about 25000 units/ milligram claimed instantly. Therefore, due to aforementioned reasons the method of RT preparation of Chernov I remains anticipatory to said claims.

No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083.

The examiner of record can normally be reached between 8:00 a.m. and 5:00 p.m. daily except for Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri, Ph.D.

Patent Examiner

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